

**510(K) SUMMARY**

**LYMPHA PRESS MODEL 201MAX™  
COMPRESSIBLE LIMB SLEEVE DEVICE**

**510(k) Number K100677**

**Applicant's Name:** Mego Afek Ltd.  
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**MAY 20 2010**

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**Date Prepared:** March 2010  
**Trade Name:** Model Lympa Press 201MAX™A Compression Therapy Device  
**Device Common or Usual Names:** Compressible Limb Sleeve  
**Classification Name:** CFR Classification section 870.5800 (Product code JOW)  
**Classification:** Class II medical Device

**Predicate Device:**

The Lympa Press 201MAX™A Compression Therapy Device is substantially equivalent to a combination of the following predicate devices:

- Lympa Press Optimal Model 1201AP (K082149) manufactured also by Mego Afek, Ltd (Israel). Lympa Press Optimal Model 1201AP is a compressible limb sleeve, similar to the Model Lympa Press 201MAX™ Compression Therapy Device.
- Lympa Press Plus Model 1033 (K013331) manufactured also by Mego Afek, Ltd (Israel). Lympa Press Plus Model 1033 is a compressible limb sleeve, similar to the Model Lympa Press 201MAX™ Compression Therapy Device.

**Device Description:**

Mego Afek's Lympa Press 201MAX™ Compression Therapy Device utilizes an air compression pump, which sequentially inflates and deflates cells within a compression garment (sleeve) which is placed on a body part. This helps to push excessive interstitial fluid in the treated body part, back into the venous and lymphatic systems; improve fluid circulation; and thus treat the symptoms of a variety of lymphatic and venous disorders and dysfunction of the "muscle pump". The device consists of a main console and compression garments. The main console contains an air compressor that is regulated by a mechanical mechanism, pressure knobs and an LCD display. The regulated compressed air is

transferred via an air distributor through a series of hoses to the sleeve garments. In the Model Lympha Press 201MAX™ device, each garment contains up to 12 overlapping pressure cells. The sleeve fits on the affected body part and can be easily adjusted to any size within the sleeve tolerance.

**Intended Use / Indication for Use:**

Treatment of primary lymphedema, secondary lymphedema, venous insufficiency, venous stasis ulcers, dysfunction of the muscle pump.

**Performance Standards:**

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for a compressible limb sleeve device.

**Test Data:**

The Model Lympha Press 201MAX™ Compression Therapy device has been subjected to extensive safety, performance testing, and validation before release. Validation of the device software was performed according to the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (January 11, 2002) and software documentation was written according to the relevant IEEE standards. The Lympha Press 201Max™ device was tested and complies with the following standards:

- IEC/EN60601-1:1988 (am1-91, am2-95), Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03 standard.
- IEC/EN 60601-1-2 (2005/ 2001): Medical Electrical Equipment-Part 1: General requirements for safety and Part 1-2 Collateral standard: Electromagnetic Compatibility-Requirements and tests.

Performance testing of the Lympha Press 201MAX™ device included additional testing, designed to ensure that the device met all its functional specifications, including noise measurements; pressure accuracy at room temperatures (15°C & 30°C), at extreme temperature conditions (-40°C and +70°C) and at mains voltages (127V & 103V); cycle time; pressure vs. time cycle sequence; distributor failure testing; cyclic redundancy testing; sensor stability calibration testing; pressure gradient testing; and calibration procedure validation.

**Substantial Equivalence:**

The Model Lympha Press 201MAX™ Compression Therapy device is similar to currently distributed Compression Therapy devices intended for treatment of lymphatic disorders, venous disorders and dysfunction of the “muscle pump”. The device uses sequential inflation and deflation of cells within compression sleeves put around a body part. Inflation/ Deflation pressures and sequences are similar to those of predicate devices. Operating modes are similar to those of predicate devices. All of the above features are similar to these features in the predicate devices.

**Conclusions:**

The conclusions drawn from the above Performance Testing and comparison to predicate devices is that the Model Lympha Press 201MAX™ compression therapy device is substantially equivalent in safety and efficacy to the predicate devices listed above.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

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Re: K100677  
Lympha Press 201MAX™ Compression Therapy  
Device Regulation Number: 21 CFR 870.5800  
Regulation Name: Sleeve, Limb, Compressible  
Regulatory Class: Class II  
Product Code: JOW  
Dated: March 7, 2010  
Received: March 10, 2010

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

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found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K100677

Device Name: Lympha Press Model 201Max A Compression Therapy device

### Indications for Use:

Primary lymphedema

Secondary lymphedema

Venous insufficiency

Venous stasis ulcers

Dysfunction of the muscle pump

Prescription Use ✓  
(Per 21 C.F.R. 801 Subpart D)  
C)

OR

Over-The-Counter Use       
(Optional Format Subpart

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. V. [Signature]  
(Division Sign-Off)  
Division of Cardiovascular Devices

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